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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/761,978   | 01/21/2004  | Howard Cohen         | 479-P-007B          | 4044             |
| 7277   | 7590        | 11/22/2005           | EXAMINER            |                  |
| HOWARD C. MISKIN<br>C/O STOLL, MISKIN, & BADIE<br>THE EMPIRE STATE BUILDING<br>350 FIFTH AVENUE SUITE 4710<br>NEW YORK, NY 10118 |             |                      | SNOW, BRUCE EDWARD  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3738                |                  |
| DATE MAILED: 11/22/2005  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/761,978

Applicant(s)

COHEN ET AL.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 16, 21-23, 25-37 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-15, 24, 38, 39 and 43-45 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 11/7/05 have been fully considered. The objection to the drawings because they fail to show at least claims 13-15, 38, 39 has been withdrawn.

Regarding the rejection of at least claim 13 under 35 U.S.C. 112, first paragraph, the additional stabilized assembly stabilizes the plates but does not stabilize the flexible supporting means.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

At least claims 13-15, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. One of ordinary skill the art cannot conceive applicant's claim of a supplemental support in combination with elected embodiment as claimed and make and/or use the device. The additional stabilized assembly stabilizes the plates but does not stabilize the flexible supporting means.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15, 38, 39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The additional stabilized assembly stabilizes the plates but does not stabilize the flexible supporting means, therefore, is not a “means for stabilizing said flexible supporting means”.

***Allowable Subject Matter***

Claims 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5-7, 43, 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Gauchet et al (6,733,532).

Gauchet et al teaches an artificial disc for placement between adjacent vertebrae comprising:

at least one upper substantially flat plate member 4 and one lower substantially flat 4 plate members, each plate member having corresponding outer and inner bearing surfaces;

at least one flexible supporting means 12 interposed between said upper and lower plate members and abutting said corresponding inner bearing surfaces, said flexible support means flexibly and compressibly supporting said upper and lower plate members to allow compression of the adjacent vertebrae; and

at least one means for stabilizing said flexible supporting means 22 for a certain period of time to allow at least two of said outer bearing surfaces to osteo-integrate with

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the adjacent vertebrae. It is noted that applicant deleted the limitation "temporarily" describing the means for stabilizing said flexible supporting means.

Claims 1-4 and 43-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Gauchet et al (6,733,532), second interpretation.

Gauchet et al teaches an artificial disc for placement between adjacent vertebrae comprising:

at least one upper substantially flat plate member 4 and one lower substantially flat 4 plate members, each plate member having corresponding outer and inner bearing surfaces;

at least one flexible supporting means 22 interposed between said upper and lower plate members and abutting said corresponding inner bearing surfaces, said flexible support means flexibly and compressibly supporting said upper and lower plate members to allow compression of the adjacent vertebrae; and

at least one means for stabilizing said flexible supporting means 12 for a certain period of time to allow at least two of said outer bearing surfaces to osteo-integrate with the adjacent vertebrae. It is noted that applicant deleted the limitation "temporarily" describing the means for stabilizing said flexible supporting means.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 11-13 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (6,019,792) in view of Zdeblick et al (6,881,228).

Cauthen teaches an artificial disc for placement between adjacent vertebrae comprising:

at least two plate members 20, 22, each plate member having a corresponding surface:

at least one means for temporarily stabilizing said plate members for a certain period of time to allow at least two of said plate members to osteo-integrate with adjacent vertebrae (see elements 82, 94, etc and at least 3:7 et seq. and 6:43 et seq.); and

at least one flexible supporting means (see element 90 in figure 5) interposed between said plate members and abutting inner bearing surfaces, said flexible support means flexibly supporting said plate members after said certain period of time.

However, Cauthen teaches a plate members which have a generally semi-circular cross-section and not a substantially flat plate. Zdeblick et al also teaches various artificial disc prostheses having a semi-circular cross-sections (at least figures 3 and 28) like Cauthen and, additionally, teaches a flat plate configuration as shown in figures 38-41 and 7. It would have been obvious to one having ordinary skill in the art have substituted the flat plat configuration as taught by Zdeblick et al on the disc of Cauthen as a know alternative shape in the art which does not require a cylindrical removal of the vertebrae bone would deemed appropriate by the surgeon.

Regarding claim 4, the plate members are made of titanium and therefore, ball element 42 is titanium which is interpreted as a portion of the flexible supporting means.

Regarding at least claim 12, "rigid collar surrounding", see 7:7 et seq. teaching filling a biodegradable polymer between the plate members which forms a collar.

Regarding at least claim 13, "supplemental support", see the bioabsorbable endcap 90.

Regarding claim 1, "compressibly" describing the flexible supporting means, as noted by applicant, Cauthen teaches element 90 as "resilient to absorb implant loading" which is interpreted by the Examiner as "flexibly and compressibly".

Claims 24 and 14-15, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (6,019,792) and Zdeblick et al (6,881,228) and further in view of Shinn et al (5,683,465).

Cauthen and Zdeblick et al teaches the artificial disc as described above including using drugs for bone ingrowth (see 8:12 et seq.), however, they are silent regarding a "substance with anti-microbial drug eluting factors". Shinn et al teaches a similar artificial disc which uses drugs to promote healing including an antibiotic. It would have been obvious to one having ordinary skill in the art have used an antibiotic as taught by Shinn et al or any other drug known in the art of prosthetics to promote healing, lessen the chances of infection or simply improve implantation of the disc in bone.



Regarding claims 14-15 and 38-39, Cauthen teaches the artificial disc as described above including using "one or more stabilizing means for temporarily rigidly coupling the first [plate] and second [plate]. It would have been obvious to one having ordinary skill in the art to have utilized any know stabilizing means known in the art as deemed necessary by the surgeon. Additionally, lacking any criticality in the specification, the use of the specifically claimed supplemental support.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gauchet et al (either interpretation) in view of Shinn et al (5,683,465).

Gauchet et al teaches the artificial disc as described above, however, is silent regarding a "substance with anti-microbial drug eluting factors". Shinn et al teaches a similar artificial disc which uses drugs to promote healing including an antibiotic. It would have been obvious to one having ordinary skill in the art have used an antibiotic as taught by Shinn et al or any other drug know in the art of prosthetics to promote healing, lessen the chances of infection or simply improve implantation of the disc in bone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal flourish extending to the right.

BRUCE SNOW  
PRIMARY EXAMINER